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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,132

08/28/2006

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EXAMINER

SU, SUSAN SHAN

ART UNIT

PAPER NUMBER

3761

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,132	Applicant(s) RICHARD, PATRICE	
	Examiner SUSAN SU	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Amendment to the Specification filed on June 17, 2008 is acknowledged.

Status of Claims

Claims 1-19 are pending (Claims 1, 13, & 17 are independent), wherein Claims 1-8 are amended, Claims 9-10 are original, and Claims 11-19 are new. No new matter has been added by the amendments. All claims are examined on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-7 & 11-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre (US 7,131,958) in view of Seddon et al. (US 6,024,731, "Seddon").

Regarding Claims 1-2 & 11-16, Deverre teaches a placental-blood extraction device comprising at least one extraction needle (4 or 5) for piercing the vein of the

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umbilical cord or of the placenta, a collection vessel (1) connected to said at least one needle via at least one tube (2). However, Deverre does not teach suctions means connected to said at least one needle. Seddon teaches a suction means (vacuum created inside the bottle 1, Col. 5 line 2), which is a vacuum bottle is of the Redon type (see Fig. 1 & Col. 5 lines 1-3) that simultaneously forms a collection vessel, for sucking blood so as to feed a collection vessel (1). Seddon also teaches that the suction means further comprises a vacuum pump (Col. 1 line 14). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre with the suctions means of Seddon for the purpose of speeding up placental blood collection (suction draws fluid faster than gravity or natural muscle contractions) and sustaining that speed with the addition of a pump. After the modification, the suction means will be connected to the at least one extraction needle and the entire device will be for sucking placental blood.

Regarding Claims 3 & 4, Deverre also teaches that the device includes at least one injection or extraction site (8 or 12 in Fig. 2) provided on the tube (2) between said at least one extraction needle (4 or 5) and said collection vessel (1).

Regarding Claim 5, Seddon also teaches that the at least one injection or extraction site (opening that connects tube 3 to bottle 1) is provided on the collection vessel (1). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre with Seddon for the purpose of allowing a practitioner to take out a small sample of the collected blood for diagnostic testing (cell count, genetic disease, check for contamination, etc.).

Regarding Claim 6, Deverre also teaches that the at least one injection or extraction site (12) is used to inject an anti-coagulant (Col. 3 lines 23-27) or to extract a sample of blood for analysis or to extract the blood contained in said collection vessel.

Regarding Claim 7, Deverre also teaches that the device includes blood-flow control means (13a or 14a).

Regarding Claims 17-19, the method of providing an extraction device, which comprises the structural elements of Claims 1-2 & 12, is obvious over Deverre and Seddon, as explained above. Deverre also teaches the step of piercing the vein of the umbilical cord or of a placenta (Col. 3 lines 50-51).

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre and Seddon as applied to claim 1 above, and further in view of Darling, Jr. (US 6,213,986, "Darling"). Deverre and Seddon do not teach that the blood-flow control means or the suction control means include a knurled adjustment wheel. Darling teaches a fluid-flow control means (10, Fig. 1) that includes a knurled adjustment wheel (110, Figs. 2-3). Furthermore, knurled adjustment wheels are commonly used in everyday life for fluid control, such as faucet knobs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre and Seddon with Darling for the purpose of having a way to control the amount of flow with an easy-to-grip knob.

5. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre and Seddon as applied to claim 1 above, and further in view of Van Der Heiden et al. (US 5,879,318, "Van Der Heiden").

Regarding Claim 9, Deverre and Seddon do not expressly teach that the collection vessel contains an anti-coagulant before receiving the placental blood. Van Der Heiden teaches a collection vessel (14) containing an anti-coagulant (15) before receiving said placental blood (Col. 5 lines 18-19). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre and Seddon for the purpose of properly preserving the blood for future use.

Regarding Claim 10, Deverre and Seddon do not expressly teach that the device is packaged in sterile manner and is assembled in a single package so as to be ready to use once said package has been opened. Van Der Heiden teaches packaging a cord blood collection device in a sterile manner (Col. 6 lines 15-17) and is assembled in a single package that is ready to use (suggested by Col. 6 lines 35-36 because sterility for the entire closed system can be kept only if the system is already closed before the sterilization process and kept sterilized as a single connected system). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre and Seddon with Van Der Heiden for the purpose of preventing contamination of the device and subsequently the contents inside the device.

Response to Arguments

6. Applicant's arguments filed June 17, 2008 have been fully considered but they are not persuasive. The Examiner disagrees that one of ordinary skill in the art would not find it obvious to combine the gravity-dependent blood extraction device with a vacuum to assist with the extraction. It is asserted by the Examiner that the use of suction or vacuum is conventional knowledge, such as in tear droppers and children's

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squirt toys. Furthermore, since placental blood extraction and wound drainage are both in the medical field, one of ordinary skill in using a wound drainage system would also be one of ordinary skill in using placental blood extraction device, e.g. patient-care and medical professionals. Therefore one of ordinary skill in the field would have the understanding the concept of applying suction increases the speed of fluid collection, be it blood or pus or other forms of body exudates. In this case, it is desirable to collect the blood soon after the placenta is removed from the mother's body to lower the possibility of contamination or blood coagulation, therefore making it obvious for one to look for ways to quicken the blood collection process. With regard to the Applicant's argument that the vacuum bottle taught by Seddon is not obvious to be used in connection with a needle, the Examiner also disagrees. It is obvious that a vacuum bottle can be connected to any type of opening, whether the opening is located in a needle or a tube or a sponge. The amount of suction is based on the size of the opening and the negative pressure inside the vacuum bottle, but the principle does not change with the type of the opening. In view of the aforementioned conventional knowledge, the Examiner maintains that the claimed invention is obvious over prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761